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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,502	07/27/2006	Marc Bohner	LUS-16768	2019
40854 7590 09/23/2008 RANKIN, HILL, & CLARK LLP 38210 Glenn Avenue WILLOUGHBY, OH 44094-7808				
EXAMINER				
MERENE, JAN CHRISTOP L				
ART UNIT		PAPER NUMBER		
3733				
MAIL DATE		DELIVERY MODE		
09/23/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/597,502

Applicant(s)

BOHNER ET AL.

Examiner

JAN CHRISTOPHER MERENE

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on July 27, 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s)/Mail Date 7/27/2007

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This is the initial Office action based on the 10/597,502 application filed on July 27, 2006, which is a 371 of PCT/CH04/00067 filed on February 6, 2004.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "Luer lock adapted without an internal conical element" as discussed in claim 8 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3-4, 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 3-4, 11-12 the phrase "*preferentially between*" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1, 2, 5-10, 13-16** are rejected under 35 U.S.C. 102(b) as being anticipated by Whitney US 4,220,151.

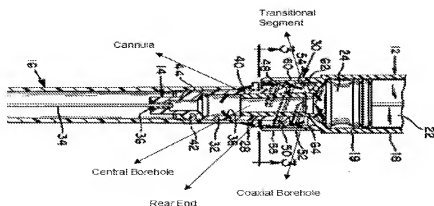
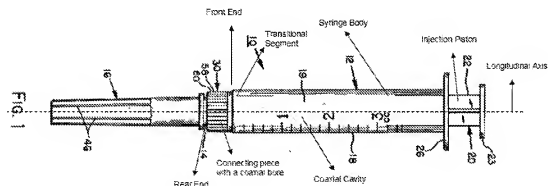
Regarding **Claim 1**, Whitney discloses an injection device especially for bone cement, comprising: A) a syringe body with a longitudinal axis, a front end, a connecting piece, disposed at the front end and having a coaxial borehole, and a coaxial cavity; B) an injection piston, which can be shifted coaxially in the cavity; and

Art Unit: 3733

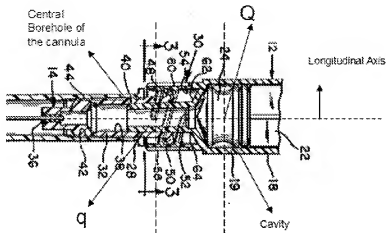
C) a cannula, which can be connected with the connecting piece, with a central borehole and rear end; wherein

D) the front end of the syringe body has a transition segment with a coaxial borehole with constant diameter, connecting the cavity with the borehole in the connecting piece; and wherein

E) the borehole in the transition segment and the central borehole have the same cross-sectional area orthogonal to the longitudinal axis at least at the rear end of the cannula (as seen in Figs below and see also Fig 4, where the transitional segment has a borehole with a constant diameter that is the same as the bore hole of the connecting piece).



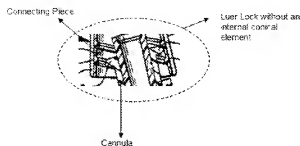
Regarding **Claim 2**, Whitney discloses the central borehole of the cannula has a constant cross-sectional area q in the axial direction (as seen below).



Regarding **Claim 5**, Whitney discloses the borehole has an internal thread (#52) in the connecting piece (see Col 2 lines 66-67 and Figs in Claim 1)

Regarding **Claims 6-7, 10**, Whitney discloses means for screwing the cannula into the internal thread, where the means is an external thread (#50 see Col 2 lines 66-67, Col 3 lines 1-2) complementary to the internal thread and means for screwing into the internal thread are constructed as a luer lock (see Col 2 lines 66-67 - Col 3 lines 1-2).

Regarding **Claim 8**, Whitney discloses the connecting piece is constructed as a luer adapter without an internal conical element (see Col 2 lines 66-67 and see fig below, where the connecting piece does not have an internal conical element).



Regarding **Claim 9**, Whitney discloses the diameter of the borehole (9) in the transition segment and the geometry of the internal thread in the connecting piece (8) correspond to those of a luer lock connection (as seen in Figs above in Claim 1 and see Col 2 lines 66-67 - Col 3 lines 1-2).

Regarding **Claims 13-14**, Whitney discloses the diameter of the borehole in the transition segment and the geometry of the internal thread in the connecting piece correspond to those of a luer lock connection (as seen in Figs above in Claim 1 and see Col 2 lines 66-67 - Col 3 lines 1-2).

Regarding **Claims 15-16**, Whitney discloses the means for screwing into the internal thread are constructed as a luer lock adapter (as seen in Figs above in Claim 1 and see Col 2 lines 66-67 - Col 3 lines 1-2).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 3-4, 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitney US 4,220,151.

Whitey discloses the claimed invention as discussed in claims 1 and 2 above, wherein the central borehole of the cannula has a constant cross sectional area q in the axial direction and the cavity of the body has a cross-sectional area Q as shown in the

Figure in Claim 2, but does not explicitly disclose the ratio of the cross sectional areas $q:Q$ is between 1 and 0.01/ between 0.2 and 0.033.

However, it is clear that from the Figs that q has a smaller cross sectional area than Q , where it would be obvious that the ration between $q:Q$ could be between 1 and .01/ 0.2 and .033.

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to have the ratio of the cross sectional areas $q:Q$ to be between 1 and 0.01 and/or 0.2 and 0.033, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733